K042733

NOV 1 5 2004

Subject: 510(k) Summary of Safety and Effectiveness Information for the Standard Imaging PIPSpro QA Software System

Proprietary Name: Standard Imaging PIPSpro QA Software System

Common Name: Portal Imaging Processing System

Classification Name: Multiple

Classification: Class I, 21CFR892.1940 – LHO, Radiologic Quality Assurance Instrument
Class I, 21CFR892.1950 – IXG, Radiographic Anthropomorphic Phantom
Class I, 21CFR892.2010 – LMB, Medical Image Storage Device
Class I, 21CFR892.2020 – LMD, Medical Image Communications Device
Class II, 21CFR892.5050 – MUJ, Accessory to a Medical Charged-Particle Therapy System
Class II, 21CFR892.2050 – LLZ, Picture Archiving and Communications System

Panel: Radiology

Contact Person: Raymond Riddle, Vice President, Regulatory Affairs

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Standard Imaging PIPSpro QA Software System is substantially equivalent to selected functions of the following predicate devices for classifications 21CFR892.5050 – MUJ and 21CFR892.2050 - LLZ:

Product Name	Manufacturer Name	FDA 510(k) Clearance	FDA 510(k) Number
Elekta iView/iView+ Electronic Portal Imaging Device	Elekta Oncology Systems, Ltd.	Yes	K012289 K981790
Portalvision Electronic Portal Imaging Device	Varian Medical Systems, Inc.	Yes	K003636 K955774
RIT113 Radiation Film Dosimetry Software	Radiological Imaging Technology, Inc.	Yes	K935928

Radiation Calibration and QA Instruments
COMPLETE SOLUTIONS PROVIDED for health care
7601 Murphy Drive • Middleton, WI 53562-2532 • Tel (608) 831-0025 • (800) 261-4446 • Fax (608) 831-2202 www.standardimaging.com

PIPSpro QA Software System (Portal Imaging Processing System, professional version) is a stand-alone software program for use on PC computers running under Microsoft Windows 9x/Me/2000/NT/XP. The PC is not supplied with PIPSpro, and must be provided by the user. PIPSpro is supplied on a CD together with a software security key ("dongal" or hard lock) which is inserted into a parallel or USB port on the computer to allow the software to work. PIPSpro does not use, control, or operate any hardware, it is purely a stand-alone software program.

AQUA is also a stand-alone software program, consisting of a small part of the PIPSpro system. AQUA includes only those routines required for the analysis of images acquired with the QC-3 phantom, and used for quality control of electronic portal imaging devices

The PIPSpro QA Software System, which displays, enhances and analyses portal images, and is used in conjunction with commercially available electronic portal imaging detectors (EPIDs). PIPSpro provides numerous measurement tools, image processing routines, statistical analysis and capabilities that are not available in the standard software provided by the EPID suppliers. These include the processing of simulator and portal verification images, analyzing patient registration errors, measuring of image quality from an EPID during installation tests, providing a platform for quality assurance programs in radiation therapy, and tools for writing and editing notes attached to images for easy communication. In this capacity, it can only import images and information.

The Standard Imaging PIPSpro QA Software System was designed to comply with the applicable portions of the following voluntary standard:

1. IEC 60601-1-4 (Edition 1.1 2000-04) – Collateral standard for programmable medical systems

The Standard Imaging PIPSpro QA Software System has been validated through nearly 10 years of evolving development and use. This validation included the following:

1. Algorithm and image transfer
2. Results presentation and graphing
3. Beta testing
4. Interface, compatibility, use and misuse
5. Bug, Modification and/or Addition change testing

The Standard Imaging PIPSpro QA Software System has met its predetermined design specifications, risk analysis and validation objectives.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2004

Raymond T. Riddle, PE, RAC
Vice President, Regulatory Affairs
Standard Imaging, Inc.
7601 Murphy Drive
MIDDLETON WI 53562-2532

Re: K042733
Trade/Device Name: Standard Imaging PIPSpro QA Software System
Regulation Number: 21 CFR 892.1940
Regulation Name: Radiologic quality assurance instrument
Product Code: 90 LHO
Regulatory Class: I
Regulation Number: 21 CFR 892.1950
Regulation Name: Radiographic anthropomorphic phantom
Product Code: 90 IXG
Regulatory Class: I
Regulation Number: 21 CFR 892.2010
Regulation Name: Medical image storage device
Product Code: 90 LMB
Regulatory Class: I
Regulation Number: 21 CFR 892.2020
Regulation Name: Medical image communications device
Product Code: 90 LMD
Regulatory Class: I
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Product Code: 90 LLZ
Regulatory Class: II
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Product Code: 90 IYE
Regulatory Class: II
Dated: September 29, 2004
Received: October 1, 2004

Dear Mr. Riddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the

Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042733

Device Name: Standard Imaging PIPSpro QA Software System

Indications For Use:

PIPSpro QA Software System (Portal Imaging Processing System, professional version) is a stand-alone software program for use on PC computers running under Microsoft Windows 9x/Me/2000/NT/XP. The PC is not supplied with PIPSpro, and must be provided by the user. PIPSpro is supplied on a CD together with a software security key ("dongal" or hard lock) which is inserted into a parallel or USB port on the computer to allow the software to work. PIPSpro does not use, control, or operate any hardware, it is purely a stand-alone software program.

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Prescription Use ✓ and/or Over-the-Counter-Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042733